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PATENT
ATTORNEY DOCKET NO.: TNX00-04
CUSTOMER NO: 26839

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:
FUNG, Michael, et al.)
Serial No.: 09/816,839)
Filed: March 23, 2001)
For: ANTI C2/C2a INHIBITORS OF
COMPLEMENT ACTIVATION)
) 06/05/2001 BSAYASI1 00000036 09816839
) 04 FC:126 180.00 OP

Assistant Commissioner for Patents
Washington, D.C. 20231

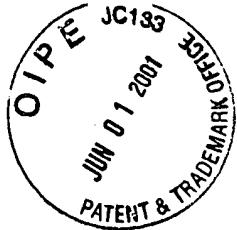
Dear Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicants submit the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed within three months of the filing date of the above-referenced application. A fee of \$180.00 is attached.

Copies of the listed documents are attached. Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached PTO 1449 form.

This submission does not represent that a search has been made or that no other documents exist which may be material to the examination of this application and does not constitute an admission that any of the listed documents, or any part thereof, are material or constitute prior art under title 35 of the United States code. Applicants reserve the right to present evidence that any of such documents are not prior art.



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Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Respectfully Submitted,

Dated: June 1, 2001.

BY: Cheryl A. Liljestrand
Cheryl A. Liljestrand
Reg. No. 45,275



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| Application Number | 09/816,839 |
| Filing Date | MARCH 23, 2001 |
| First Named Inventor | Michael FUNG, et al. |
| Group Art Unit | 1645 |
| Examiner Name | NOT YET ASSIGNED |
| Attorney Docket Number | TNX 00-04 |

U.S. PATENT DOCUMENTS

| Examiner Initials | U.S. Documents | | U.S. Patent Document Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|-------------------|----------------|-------------------------|--|---|---|
| | Number | Kind Code (if known) | | | |
| | 5,225,539 | B1 | G. WINTER | July 6, 1993 | |
| | 5,530,101 | B1 | C. QUEEN, et al. | June 25, 1996 | |
| | 4,946,778 | B1 | LADNER, et al. | AUG. 7, 1990 | |
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FOREIGN DOCUMENTS

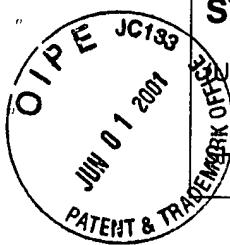
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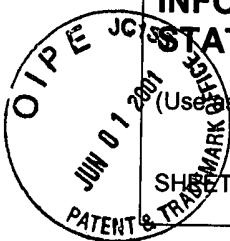
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

| Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, volume-issue number(s), page(s). | T ₂ |
|--------------------|----------|---|----------------|
| | 1 | M. MATSUSHITA, "The Lectin Pathway of the Complement System", <i>Microbiol. Immunol.</i> 40(12):887-893 (1996). | |
| | 2 | M. MATSUSHITA, et al., "MASP-1 (MBL-Associated Serine Protease-1)", <i>Immunobiol.</i> 199:340-347 (1998). | |
| | 3 | C. SUANKRATAY, et al., "Requirement for the Alternative Pathway as well as C4 and C2 in Complement-Dependent Hemolysis via the Lectin Pathway", <i>J. Immunol.</i> 160:3006-3013 (1998). | |
| | 4 | Y. ZHANG, et al., "Lysis via the Lectin Pathway of Complement Activation: minireview and lectin pathway enhancement of endotoxin-initiated hemolysis", <i>Immunopharmacol.</i> 42:81-90 (1999). | |
| | 5 | Y. ZHANG, et al., "Calcium-Independent Haemolysis via the Lectin Pathway of Complement Activation in the Guinea-Pig and Other Species", <i>Immunol.</i> 97:686-692 (1999). | |
| | 6 | HANS-PETER HEINZ, et al., "Monoclonal Antibodies Against Components of the Classical Pathway of Complement", <i>Complement Inflamm.</i> 6:166-174 (1989). | |
| | 7 | V.M. HOLERS, "Complement", IN: <u>CLINICAL IMMUNOLOGY: PRINCIPLES AND PRACTICE</u> , R.R. RICH Ed., MOSBY PRESS, 1996, pp. 363-391. | |
| | 8 | VORUP-JENSEN, et al., "MASP-2, the C3 Convertase Generating Protease of the MBlectin Complement Activating Pathway", <i>Immunobiol.</i> 199: 348-357 (1998). | |
| | 9 | C. SUANKRATAY, et al., "Complement Regulation in Innate Immunity and the Acute-Phase Response: Inhibition of Mannan-Binding Lectin-Initiated Complement Cytolysis of C-Reactive Protein", <i>Clin. Exp. Immunol.</i> 113:353-359 (1998). | |
| | 10 | C. SUANKRATAY, et al., "Mechanism of Complement-Dependent Haemolysis via the Lectin Pathway: Role of the Complement Regulatory Proteins", <i>Clin. Exp. Immunol.</i> 117: 442-448 (1999). | |
| | 11 | R. SCHLINDER, et al., "Recombinant C5a Stimulates Transcription Rather Than Translation of Interleukin-1 (IL-1) and Tumor Necrosis Factor: Translational Signal Provided by Lipopolysaccharide or IL-1 Itself", <i>Blood</i> 76:1631-1638 (1990). | |
| | 12 | T. WIEDMER et al., "Participation of Protein Kinases in Complement C5b-9-Induced Shedding of Platelet Plasma Membrane Vesicles", <i>Blood</i> 78:2880-2886 (1991). | |
| | 13 | M. P. FLETCHER, et al., "C5a-Induced Myocardial Ischemia: Role for CD18-Dependent PMN Localization and PMN-Platelet Interactions", <i>Am. J. Physiol.</i> 265:h1750-1761 (1993). | |
| | 14 | S. NAGASAWA, et al., "Cleavage of C2 by C1s into Antigenically Distinct Fragments C2a and C2b: Demonstration of Binding of C2b to C4b", <i>Proc. Natl. Acad. Sci. (USA)</i> 74:2998-3001 (1977). | |
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| | 15 | E. I. STENBAEK, et al., "Human Complement Component C2: Production and Characterization of Polyclonal and Monoclonal Antibodies Against C2", <i>Mol. Immunol.</i> 23:879-886 (1986). | 7 |
| | 16 | T. J. OGLESBY, et al., "Evidence for a C4b Binding Site on the C2b Domain of C2", <i>J. Immunol.</i> 141:926-931 (1988). | 9 |
| | 17 | Y. WANG, et al., "Amelioration of Lupus-Like Autoimmune Disease in NZB/W F ₁ Mice After Treatment With a Blocking Monoclonal Antibody Specific for Complement Component C5", <i>Proc. Natl. Acad. Sci. (USA)</i> , 1996, 93:8563-8568 | / |
| | 18 | C. S. RINDER, et al., "Blockade of C5a and C5b Generation Inhibits Leukocyte and Platelet Activation During Extracorporeal Circulation", <i>J Clin. Invest.</i> 96:1564-1572 (1995). | 7 |
| | 19 | J. C. K. FITCH, et al., "Pharmacology and Biological Efficacy of a Recombinant, Humanized, Single-Chain Antibody C5 Complement Inhibitor in Patients Undergoing Coronary Artery Bypass Graft Surgery with Cardiopulmonary Bypass", <i>Circulation</i> 100:2499-2506 (1999). | 9 |
| | 20 | H. L. LAZAR, et al., "Total Complement Inhibition: An Effective Strategy to Limit Ischemic Injury During Coronary Revascularization on Cardiopulmonary Bypass", <i>Circulation</i> 100:1438-1442 (1999). | / |
| | 21 | T. J. KROSHUS, et al., "Complement Inhibition with an Anti-C5 Monoclonal Antibody Prevents Acute Cardiac Tissue Injury in an Ex Vivo Model of Pig-To-Human Xenotransplantation", <i>Transplantation</i> 60:1194-1202 (1995). | 7 |
| | 22 | J. W. HOMEISTER, et al., "Soluble Complement Receptor Type 1 Prevents Human Complement-Mediated Damage of the Rabbit Isolated Heart", <i>J. Immunol.</i> 150: 1055-1064 (1993). | 9 |
| | 23 | H. F. WEISMAN, et al., "Soluble Human Complement Receptor Type 1: In Vivo Inhibitor of Complement Suppressing Post-Ischemic Myocardial Inflammation and Necrosis", <i>Science</i> 249:146-151 (1990). | / |
| | 24 | E. A. AMSTERDAM, et al., "Limitation of Reperfusion Injury by a Monoclonal Antibody to C5a during Myocardial Infarction in Pigs", <i>Am. J. Physiol.</i> 268: H448-H457 (1995). | 7 |
| | 25 | R. RABINOVICI, et al., "Role of Complement in Endotoxin/Platelet-Activating Factor-Induced Lung Injury", <i>J. Immunol.</i> 149:1744-1750 (1992). | 9 |
| | 26 | B. P. MORGAN, "Clinical Complementology: Recent Progress and Future Trends", <i>Eur. J. Clin. Invest.</i> 24:219-228 (1994). | / |
| | 27 | S. M. CANFIELD, et al., "The Binding Affinity of Human IgG for its High Affinity Fc Receptor is Determined by Multiple Amino Acids in the C _h 2 Domain and is Modulated by the Hinge Region", <i>J. Exp. Med.</i> 173:1483-1491 (1991). | 7 |
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|--------------------|----------|---|-----|
| | 28 | KOHLER AND MILSTEIN, "Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity", <i>Nature</i> 256: 495-497 (1975). | |
| | 29 | Y. XU, et al., "Residue at Position 331 in the IgG1 and IgG4 C _H 2 Domains Contributes to Their Differential Ability to Bind and Activate Complement", <i>J. Biol. Chem.</i> 269:3469-3474 (1994). | |
| | 30 | V. L. PULITO, et al., "Humanization and Molecular Modeling of the Anti-CD4 Monoclonal Antibody, OKT4A", <i>J. Immunol.</i> 156:2840-2850 (1996). | |
| | 31 | L. RIECHMANN, et al., "Reshaping Human Antibodies for Therapy", <i>Nature</i> 332:323-327 (1988). | |
| | 32 | M. J. EVANS, et al., "Rapid Expression of an Anti-Human C5 Chimeric Fab Utilizing a Vector That Replicates in COS and 293 Cells", <i>J. Immunol. Meth.</i> 184:123-138 (1995). | |
| | 33 | S.K. DATTA, "Murine Lupus", <i>Meth. Enzymol.</i> 162:385-413 (1988). | |
| | 34 | D. J. SALVANT, et al., "Experimental Glomerulonephritis", <i>Meth. Enzymol.</i> 162:421-461 (1988). | |
| | 35 | Y. WANG, et al., "Anti C5 Monoclonal Antibody Therapy Prevents Collagen-Induced Arthritis and Ameliorates Established Disease", <i>Proc. Natl. Acad. Science (USA)</i> 92:8955-8959 (1995). | |
| | 36 | M. S. MULLIGAN, et al., "Protective Effects of Soluble CR1 in Complement- and Neutrophil-Mediated Tissue Injury", <i>J. Immunol.</i> 148:1479-1485 (1992). | |
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